IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNITED STATES OF AMERICA ex rel. LAYNE FOOTE, et al., Plaintiffs, v. ASTRAZENECA LP AND ASTRAZENECA PHARMACEUTICALS LP, Defendants.	C.A. No. 1:10-cv-00095 (SLR)

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE THIRD AMENDED COMPLAINT PURSUANT TO RULES 8, 9, 12(b)(1) &(6)

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MORGAN, LEWIS & BOCKIUS LLP

Jody C. Barillare (#5107)
The Nemours Building
1007 N. Orange Street, Suite 501
Wilmington, DE 19801
(302) 574-3000
jbarillare@morganlewis.com

John C. Dodds (admitted *pro hac vice*)
Rebecca J. Hillyer (admitted *pro hac vice*)
Evan K. Jacobs (admitted *pro hac vice*)
1701 Market Street
Philadelphia, PA 19103-2921
(215) 963-5000
jdodds@morganlewis.com
rhillyer@morganlewis.com
ejacobs@morganlewis.com

Attorneys for Defendant AstraZeneca Pharmaceuticals LP

TABLE OF CONTENTS

Page

TABLE OF CONTENTS
(continued)

Page

TABLE OF AUTHORITIES

Page(s)

CASES

TABLE OF AUTHORITIES
(continued)

Page(s)

TABLE OF AUTHORITIES
(continued)

Page(s)

TABLE OF AUTHORITIES
(continued)

Page(s)

STATUTES

TABLE OF AUTHORITIES
(continued)

Page(s)

OTHER AUTHORITIES

I. STATEMENT OF THE NATURE AND STAGE OF THE PROCEEDINGS

Relator Layne Foote filed this *qui tam* action against defendants AstraZeneca LP and AstraZeneca Pharmaceuticals LP ("AstraZeneca") alleging False Claims Act ("FCA") and state law violations relating to the promotion of Crestor. Foote filed his original complaint on February 5, 2010. D.I. 2. Foote amended his complaint on March 30, 2010 to add a second relator, Mark T. Lorden, and add new claims and allegations related to Lorden's purported knowledge. *See* D.I. 7. Relators filed a Second Amended Complaint ("SAC") on October 6, 2010. D.I. 19. The government and the named states declined to intervene and the case was unsealed on October 31, 2013.[1] D.I. 50. On January 5, 2015, AstraZeneca filed its Motion to Dismiss, which identified fatal and insurmountable defects in the SAC. *See* D.I. 63. Relators amended for a third time on March 5, 2015. *See* Third Amended Complaint ("TAC"), D.I. 68. The TAC fails for the same reasons as the SAC – Relators cannot allege "reliable indicia that lead to a ***strong inference***" that false claims were actually submitted because Relators' allegations are equally consistent with an inference that only lawful claims were submitted to government programs. *See Foglia v. Renal Ventures Mgmt. LLC.*, 754 F.3d 153, 156 (3d Cir. 2014) (emphasis added).

This is not your typical FCA case, in which a relator may be able to satisfy the relevant pleading standard by alleging facts that rightfully lead to an inference that false claims were actually submitted to the government. Here, Relators cannot satisfy this standard because their allegations are equally (if not more) consistent with alternative and lawful explanations that do

[1] Also before this Court were four related *qui tam* actions where the government and named states also declined to intervene: *United States ex rel. De Souza v. AstraZeneca PLC, et al.*, No. 1:12-cv-00756-SLR (D. Del.) ("De Souza Action"); *United States ex rel. McDonough v. AstraZeneca LP et al.*, No. 1:10-cv-00557-RGA (D. Del.); *United States ex rel. Matesich v. Astra Zeneca Pharmaceuticals LP*, No. 1:11-cv-00650 (D. Del); *United States ex rel. Savarese v. AstraZeneca Corp.*, No. 1:11-cv-01128-SLR (D. Del). All of these cases have been dismissed.

not implicate FCA violations. This is because the alleged patient populations for Crestor's FDA-approved indications are identical to the patient populations for the "off-label" uses alleged in the TAC. Indeed, all of the alleged "off-label" uses are "medically accepted" within the meaning of the Medicaid and Medicare statutes, and therefore are as subject to government reimbursement as the FDA-approved uses. Even if off-label promotion had occurred, without specific allegations stating otherwise, any actual claims that were submitted could have been – and most likely were – for approved or medically accepted uses.

II. SUMMARY OF ARGUMENT

1. Crestor is a statin approved by the FDA for the treatment of cholesterol, slowing the progression of atherosclerosis and reducing the risk of heart attack and strokes. TAC ¶¶ 141-43. In addition, it is supported by a statutorily recognized compendium, DRUGDEX Information System ("Drugdex"), for the treatment of "generalized atherosclerosis" and "disorder of the cardiovascular system." SAC ¶ 105. Claims submitted for these uses cannot constitute false claims because they are reimbursable by government programs. *See United States ex rel. Gohil v. Sanofi-Aventis U.S., Inc.*, No. 02-2964, -- F. Supp. 3d --, 2015 WL 1456664, at *10-11 (E.D. Pa. Mar. 30, 2015).

2. Relators make three types of off-label promotion allegations: (a) that AstraZeneca promoted scientific studies to demonstrate Crestor's superior efficacy over other statins; (b) that AstraZeneca promoted scientific studies to support Crestor for the "regression of atherosclerosis" and for the treatment of heart attacks and strokes; and (c) that AstraZeneca promoted Crestor for other "pleiotropic" effects. All three of Relators' theories fail to state any FCA claim with adequate particularity or plausibility, as required by Federal Rules of Civil Procedure 8(a) and 9(b).

3. It is axiomatic, and consistent with the Third Circuit's *Foglia* standard, that "[w]here a complaint pleads facts that are 'merely consistent with' a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." *See United States ex rel. Customs Fraud Investigations, LLC v. Victaulic Co.*, No. 13-2983, 2014 WL 4375638, at *14 (E.D. Pa. Sept. 4, 2014) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007))).

4. Relators' allegations "stop short of the line between possibility and plausibility" because the most likely inference drawn from Relators' allegations is that prescriptions written by physicians were for FDA-approved or otherwise medically accepted indications which, by statutory definition, cannot constitute false claims. *See Gohil*, 2015 WL 1456664, at *10-11.

5. Critically, Relators never allege that a physician wrote a prescription for a non-reimbursable use; rather, they conclusorily allege that physicians wrote "Crestor prescriptions," which caused the submission of false claims. Moreover, despite Relators' attempts to plead away fatal yet undeniable facts alleged in the SAC, the fact that "generalized atherosclerosis" and "disorder of the cardiovascular system" are medically accepted uses for which federal programs provide reimbursement forecloses the possibility of any false claims arising from the use of Crestor for "regression of atherosclerosis" or to prevent heart attacks and strokes.

6. Relators' FCA claims based on the Anti-Kickback Statute ("AKS") fail for similar reasons. Relators have merely pled lawful conduct under the AKS and FCA. The TAC alleges a variety of lawful activity, including engaging in speaker programs, hosting dinners, and participating in CME's, without specifically alleging what makes such conduct unlawful and subject to the AKS. Without such specificity, Relators' AKS allegations must be dismissed.

7. Independent of Relators' failure to plead an FCA action with plausibility and particularity, Lorden's claims and allegations should be dismissed because they are barred by the FCA's first-to-file rule. *See* 31 U.S.C. § 3730(b)(5). Lorden's claims and allegations were filed after two related actions regarding the same material facts – the Foote and De Souza Actions – were already pending. As such, Lorden's claims must be dismissed.

8. For these reasons and as set forth below, the TAC should be dismissed under Fed. R. Civ. P. 8(a), 9(b) and 12(b)(6) and Lorden's claims should be dismissed for the additional reason that the Court lacks subject-matter jurisdiction over his claims.

III. BACKGROUND

A. Physicians Consider Off-Label Uses When Making Independent Prescribing Decisions

The FDA does not "prohibit physicians from prescribing the drug for uses that are different than those approved by the FDA." *See* TAC ¶ 57. Physicians may prescribe FDA-approved medications to treat any condition or disease – on-label or off-label – based on their independent medical judgment. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001). Off-label prescribing is a widespread and accepted medical practice. *See In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 240 (3d Cir. 2012); *United States v. Caronia*, 703 F.3d 149, 153 (2d Cir. 2012); *see also Wash. Legal Found. v. Henney*, 202 F.3d 331, 333 (D.C. Cir. 2000). Indeed, many unapproved uses reflect the standard of medical care. *See, e.g.*, Joseph W. Cranston *et al.*, Report of the Council of Scientific Affairs: Unlabeled Indications for Food and Drug Administration – Approved Drugs, 32 Drug Info. J. 1049, 1050 (1998).

Given the prevalence of off-label prescribing and its importance to the treatment of patients, the FDA recognizes "the important public health and policy justification supporting

dissemination of truthful and non-misleading medical journal articles and medical or scientific reference publications on unapproved uses." *See, e.g.*, Guidance for Industry – Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices (Jan. 2009), *available at* http://www.fda.gov/oc/op/goodreprint.html (last visited Apr. 21, 2015). Thus, manufacturers may disseminate off-label information in various ways. *See* TAC ¶ 69 (internal citation omitted); *see also* 59 Fed. Reg. 59820, 59823 (Nov. 18, 1994); Draft Guidance: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices (Dec. 2011), *available at* http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm285145.pdf (last visited Apr. 21, 2015).

B. Medicaid and Medicare Reimbursement

Medicaid provides health services for families and individuals with limited means. *See* TAC ¶ 85. Although Medicaid is administered on a state-by-state basis, the state Medicaid programs must adhere to federal guidelines. *Id.* ¶ 87. These federal statutes require reimbursement for prescription drugs which are used for "a medically accepted indication." *Id.* (citing 42 U.S.C. §§ 1396(b)(I)(10), 1396r-8(k)(2)-(3), 1396r-8(k)(3)). A medically accepted indication is a use that is listed in the labeling approved by the FDA, or that is included in one of the drug compendia identified in the Medicaid statute. *Id.* ¶ 88. One of the three statutorily named compendia is Drugdex. *Id.*

Medicare provides federally funded health insurance to the elderly and disabled. As a general matter, Medicare coverage is available for any item or service that is "reasonable and necessary for the diagnosis or treatment" of an illness. 42 U.S.C. § 1395y(a)(1)(A). Similar to Medicaid, Medicare provides reimbursement for a "covered Part D drug" that is used for a

"medically accepted indication," which is defined by reference to the Medicaid definition of a "medically accepted indication." TAC ¶ 102 (citing 42 U.S.C. § 1396r8(k)(6)). Like Medicaid, Medicare reimburses for prescription drugs "including off-label uses [that] are 'supported by one or more citations included or approved for inclusion in' one of the three compendia." TAC ¶ 102 (citing 42 U.S.C. § 1395w-102(2)(4)).

Thus, if an off-label use is supported by a statutorily recognized compendium, like Drugdex, it is reimbursable by government programs.[2]

C. Crestor's Medically Accepted Uses

The FDA has approved the use of Crestor for various indications that are relevant to this matter. Crestor was first approved in 2003 "as an adjunct to diet to reduce elevated total-C, LDL-C, ApoB, non-HDL-C, and TG levels and to increase HDL-C in patients with hypercholesterolemia (heterozygous familial and nonfamilial) and mixed dyslipidemia" and "to reduce LDL-C, total-C, and ApoB in patients with homozygous familial hypercholesterolemia as an adjunct to other lipid-lowering treatments," among other indications. TAC ¶ 141. In 2007, the FDA approved Crestor for slowing the progression of atherosclerosis as part of a treatment strategy to lower total-C and LDL-C as an adjunct to diet. *Id.* ¶ 142. In 2010, the FDA approved Crestor for primary prevention of cardiovascular disease, which includes indications to (1) reduce the risk of stroke; (2) reduce the risk of heart attack; and (3) reduce the risk of arterial revascularization procedures. *Id.* ¶ 143.

In addition to the FDA-approved uses, there are various uses supported in the statutorily

[2] This conclusion remains the same for reimbursement under CHAMPUS/Tricare and other government programs. Relators concede that "coverage of off-label drug use under these programs is similar to the coverage provided by the Medicaid Program." TAC ¶ 117. Further, courts have found that promoting a prescription drug for a medically accepted indication could not plausibly lead to the submission of false claims to CHAMPUS/Tricare or other government programs. *See Gohil*, 2015 WL 1456664, at *12.

approved compendium, which qualify as "medically accepted indications" and, thus, are reimbursable by federal programs. *See* TAC ¶¶ 87-88, 102, 515; SAC ¶ 104.[3] These uses include "generalized atherosclerosis" and "disorder of the cardiovascular system, primary: prophylaxis." *See* SAC ¶ 105.[4]

"Regression of atherosclerosis," a purported off-label use referenced by Relators throughout the TAC, is simply a result of the treatment for general atherosclerosis and cardiovascular disorders – supported compendia uses. Atherosclerosis is a cardiovascular disease or disorder in which an artery wall thickens as a result of plaque buildup. *See* STEDMAN'S MEDICAL DICTIONARY (26th ed.). Regression of Atherosclerosis refers to the decrease of the plaque buildup and a thinning of the arterial wall, which can result from statin therapy for atherosclerosis. *See Steve E. Nissen, et al., Effect of Very High-Intensity Statin Therapy on Regression of Coronary Atherosclerosis: The ASTEROID Trial*, 295 J. AM. MED. ASS'N 1556 (2006); STEDMAN'S MEDICAL DICTIONARY (defining "regression" as "a subsidence of symptoms").

The FDA-approved uses, coupled with the recognized uses in the compendium, cover myriad cardiovascular and cholesterol-related conditions, including treatment for general

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[3] Although Relators reference and rely upon Drugdex in the TAC (*see* ¶ 147), Relators deleted factual allegations from the SAC regarding Crestor's indicated uses listed in the Drugdex compendia in an attempt to plead around the dispositive fact that Drugdex supports the use of Crestor for Generalized Atherosclerosis (which includes regression of atherosclerosis and slowing the progression of atherosclerosis). *See* SAC ¶ 105. "[A] document integral to or explicitly relied upon in the complaint may be considered without converting the motion to dismiss into one for summary judgment." *See In re Burlington Coat Factory Secs. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (internal quotation and marks omitted).

[4] Drugdex supports Crestor for numerous other uses including: Acute Coronary Syndrome; Atrial Fibrillation; Prophylaxis-Operation on heart; Disorder of Cardiovascular System; Prophylaxis – Heart failure, chronic; Familial Hypercholesterolemia-Homozygous; Familial Hypercholesterolemia-Heterozygous; Familial Type 3 Hyperlipoproteinemia; Hyperlipidemia, Primary; Hypertriglyceridemia; Metabolic Syndrome; Mixed Hyperlipidemia; and Venous Thromboembolism, Prophylaxis. *See* SAC ¶ 105.

atherosclerosis and disorder of the cardiovascular system, which are proper and reimbursable by federal programs. Use of Crestor for these purposes, therefore, could not give rise to a false claim.[5]

D. Overview of Relators' Allegations

The crux of Relators' allegations is that AstraZeneca utilized major scientific studies published in reputable medical journals to promote Crestor for "superior" efficacy (TAC ¶¶ 172-282), "regression of atherosclerosis" (*id.* ¶¶ 283-335), prevention of heart attack and strokes (*id.* ¶¶ 336-97), and other "pleiotropic" effects (*id.* ¶¶ 398-434), in purported violation of FDA rules. Much of Relators' 757-paragraph TAC is devoted to rote recitals of their federal and state law claims (*id.* ¶¶ 554-757); background regarding the FDA, Medicare and Medicaid (*id.* ¶¶ 42-119); and conclusory assertions of causation (*id.* ¶¶ 515-53). An equally disproportionate number of paragraphs is devoted to suggesting that dissemination or discussion of published, peer-reviewed scientific studies by world-renowned medical researchers is somehow false or misleading, including irrelevant tangents about alleged flaws in scientists' research (*see, e.g.*, *id.* ¶¶ 228, 236, 352-73). However, Relators do not allege how such conduct led to the submission of claims for non-reimbursable uses of Crestor. Relators' AKS allegations – focused on allegations of lawful activity – similarly fail to address how such conduct establishes an AKS violation. *See id.* ¶¶ 435-511.

[5] Any allegation that use of Crestor for these purposes could result in a false claim is contradicted by Relators' factual pleadings in the SAC (¶ 105) and a plain understanding of Drugdex's supported indications. *See Goldenberg v. Indel, Inc.*, 741 F. Supp. 2d 618, 624 (D.N.J. 2010) (holding where complaint relies directly or indirectly on documents referenced in complaint, court will consider those documents "and to the extent they contradict the Complaint's factual allegations, the documents will control") (quoting *ALA, Inc. v. CCAIR, Inc.*, 29 F.3d 855, 859 n. 8 (3d Cir. 1994)). Regardless, as discussed throughout this brief, Relators never specifically allege that prescriptions were submitted for such alleged non-reimbursable uses.

IV. ARGUMENT

A. Legal Standards

1. Relevant Pleading Standards

Under Rule 8(a), a complaint must contain "sufficient factual matter, accepted as true, 'to state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). To survive a motion to dismiss under Rule 12(b)(6), a plaintiff must plead "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. 678. "[L]abels and conclusions" or "a formulaic recitation of the elements of a cause of action" do not suffice. *Id*. at 678 (quoting *Twombly*, 550 U.S. at 555); *see also James v. City of Wilkes-Barre*, 700 F.3d 675, 679 (3d Cir. 2012) ("[W]e disregard rote recitals of the elements of a cause of action, legal conclusions, and mere conclusory statements.").

In FCA cases, the particularity requirement of Rule 9(b) also applies. *See, e.g., United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 242 n.9 (3d Cir. 2004). Rule 9(b) requires that, in "alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). "'The requirements of Rule 9(b) effectively prevent a claimant from searching for a valid claim after a civil action has been commenced.'" *United States ex rel. Budike v. Peco Energy*, 897 F. Supp. 2d 300, 316 (E.D. Pa. 2012) (quoting 2 James Wm. Moore et al., *Moore's Federal Practice* § 9.03[1][a] (3d ed. 2002)).

To adequately allege an FCA case based on off-label promotion, at a minimum, relator must present specific factual allegations supporting both: (1) the alleged off-label promotion; and (2) how that off-label promotion caused the submission of false claims for government reimbursement. *See, e.g., United States ex rel. Lampkin v. Johnson & Johnson, Inc.*, Civil Action No. 08-05362, 2013 WL 2404238, at *4 (D.N.J. May 31, 2013). Thus, a relator must

plead more than unlawful promotion; he must also plead with both plausibility and particularity that the alleged unlawful promotion caused the submission of false claims. *See United States ex. rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 301 n.9, 310-11 (3d Cir. 2011).

The same pleading standards apply where the FCA claim is based on the alleged payment of kickbacks. *See United States ex rel. Wilkins v. United Health Grp., Inc.*, No. 08-3425, 2011 WL 6719139, at *2 (D.N.J. Dec. 20, 2011); *United States ex rel. Bennett v. Medtronic, Inc.*, 747 F. Supp. 2d 745, 783-85 (S.D. Tex. 2010).

2. The *Foglia* Standard

Consistent with these requirements, the Third Circuit recently held that a plaintiff must allege "particular details of a scheme to submit false claims paired with ***reliable indicia that lead to a strong inference that claims were actually submitted***." *Foglia v. Renal Ventures Mgmt. LLC.*, 754 F.3d 153, 156 (3d Cir. 2014) (emphasis added). The *Foglia* analysis entails evaluating the complaint to determine whether the inference suggesting FCA liability overcomes any competing inference of lawful conduct. *See id.* at 157-58.

Foglia is consistent with the pleading principles affirmed in *Iqbal* and *Twombly* and their progeny, including in FCA cases: "[w]here [] the complaint pleads facts that are 'merely consistent with' a defendant's liability, the plaintiff has failed to state a claim." *See United States ex rel. Customs Fraud Investigations, LLC v. Victaulic Co.*, No. 13-2983, 2014 WL 4375638, at *15 (E.D. Pa. 2014) (quoting *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 557)); *see also Gonzalez v. Planned Parenthood of Los Angeles*, 759 F.3d 1112, 1116 (9th Cir. 2014) (affirming dismissal of FCA claims where plaintiff's allegation that defendants knowingly submitted false claims was only "merely *possible* rather than plausible" because plaintiff could not overcome the plausible and obvious alternative explanation that defendants did not knowingly submit false claims (emphasis in original)); *United States ex rel. Nathan v. Takeda*

Pharms. N.A., Inc., 707 F.3d 451, 457 (4th Cir. 2013) ("[W]hen a defendant's actions, as alleged and as reasonably inferred from the allegations, *could* have led, but *need not necessarily* have led, to the submission of false claims, a relator must allege with particularity that specific false claims actually were presented to the government for payment." (emphasis in original)). In *Foglia*, the relator alleged specific facts to discount the inference of lawful conduct. *See Foglia*, 754 F.3d at 158. Relators' TAC is devoid of any such allegations.

3. Off Label Promotion Does Not Give Rise to FCA Liability Without a False Claim

"The submission of a false claim is a necessary element to state a cause of action under [the FCA]." *United States ex rel. Gohil v. Sanofi-Aventis U.S., Inc.*, No. 02-2964, -- F. Supp. 3d --, 2015 WL 1456664, at *10 (E.D. Pa. Mar. 30, 2015). Liability under the FCA "does not attach to violations of federal law or regulations, such as marketing of drugs in violation of the [Food, Drug and Cosmetic Act ('FDCA')], that are independent of any false claims." *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 727 (1st Cir. 2007), *overruled on other grounds by Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662 (2008). Thus, allegations of off-label promotion alone are not sufficient to establish a violation of the FCA. *See, e.g.*, *Indiana/Kentucky/Ohio Reg'l Council of Carpenters Welfare Fund v. Cephalon, Inc.*, Civil Action No. 13–7167, 2014 WL 2115498, at *6 (E.D. Pa. May 21, 2014) ("Importantly, while [defendant's] actions may well constitute improper off-label promotion under the FDCA and its regulations, we reiterate that it does not follow that the promotion is fraudulent."); *Cent. Reg'l Emps. Benefit Fund v. Cephalon, Inc.*, Civil Action No. 09-3418, 2010 WL 1257790, at *4 (D.N.J. Mar. 29, 2010) ("[I]t is well-established that 'off-label marketing of an approved drug is itself not inherently fraudulent'") (quoting *In re Actimmune Mktg. Litig.*, 614 F. Supp. 2d 1037, 1051 n.6 (N.D. Cal. 2009)); *see also Caronia*, 703 F.3d at 165 ("[P]romoting off-label drug use

concerns lawful activity (off-label drug use), and the promotion of off-label drug use is not in and of itself false or misleading."); *United States ex rel. Polansky v. Pfizer, Inc.*, No. 04-cv-0704, 2009 WL 1456582, at *6 (E.D.N.Y. May 22, 2009) (explaining that "the FDA has acknowledged that 'accepted medical practice often includes drug use that is not reflected in approved drug labeling'") (internal citation omitted).[6]

4. Claims for Medically Accepted Uses Are Not False Claims

A claim for an off-label use that is federally reimbursable is not a false claim as a matter of law. *See, e.g.*, *Gohil*, 2015 WL 1456664, at *11 ("Since the claims would have been eligible for reimbursement, it is simply implausible that the marketing scheme could have caused the submission of false or fraudulent claims"); *United States ex rel. Banigan v. Organon USA Inc.*, 883 F. Supp. 2d 277, 294 (D. Mass. 2012) ("[I]f a state Medicaid program chooses to reimburse a claim for a drug prescribed for off-label use, then that claim is not 'false or fraudulent,' and liability cannot therefore attach for reimbursement."); *United States ex rel. Nathan v. Takeda Pharms. N.A., Inc.*, No. 1:09-cv-1086, 2011 WL 2182422, at *3 (E.D. Va. May 4, 2011) (dismissing relator's FCA claims because "Relator fail[ed] to plead facts that would establish that off-label prescriptions for [the drug] were not reimbursable under each of the government programs that Relator identifies"); *United States ex rel. King v. Solvay S.A.*, 823 F. Supp. 2d 472, 510 (S.D. Tex. 2011) ("If an off-label use is supported by DRUGDEX or another approved compendia, then it is a 'medically accepted indication,' and claims for payment of medically accepted indications are not false claims"), *order vacated in non-relevant part on reconsideration by* 2012 WL 1067228 (S.D. Tex. Mar. 28, 2012); *United States ex rel. Hess v.*

[6] Moreover, truthful, non-misleading promotion of pharmaceutical products, including promotion for off-label uses, is protected speech safeguarded by the First Amendment. *See Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2659 (2011); *see also In re Schering Plough Corp.*, 678 F.3d at 240; *Caronia*, 703 F.3d at 160 (construing the FDCA as not "criminalizing the simple promotion of a drug's off-label use because such a construction would raise First Amendment concerns").

Sanofi-Synthelabo Inc., No. 4;05CV570MLM, 2006 WL 1064127, at *9 (E.D. Mo. Apr. 21, 2006) (holding FCA claims fail to extent they extend after date Medicare administrator included off-label uses of drug at issue for reimbursement).

For Relators to plausibly state an FCA claim, they must allege that claims were submitted to government payors for off-label uses that are not "medically accepted" and, thus, not reimbursable under federal programs. *See Gohil*, 2015 WL 1456664, at *11 (E.D. Pa. Mar. 30, 2015) (dismissing FCA claims where complaint only specifies off-label uses which were medically accepted indications).

B. Relators' Claims Should be Dismissed for Failure to State Any FCA Claims with Plausibility or Particularity Under Fed. R. Civ. P. 8(a) and 9(b)

While the Third Circuit does not require Relators to identify specific false claims that were submitted to a government program, Relators still must allege reliable indicia that lead to a strong inference that false claims were submitted. *See Foglia*, 754 F.3d at 156. Here, the patient populations for FDA-approved uses and the alleged off-label uses overlap entirely, and even the alleged off-label uses are medically accepted. Accordingly, Relators cannot establish a strong inference that false claims were submitted, since it is as likely that physicians wrote prescriptions for reimbursable uses as for non-reimbursable uses.

1. Relators' "Superiority" Allegations Do Not Lead to a Strong Inference that False Claims Were Submitted to the Government

Relators spend 110 paragraphs attempting to describe a misbranding scheme whereby AstraZeneca allegedly used published scientific studies, such as STELLAR and JUPITER, to market Crestor as superior to other statins. *See* TAC ¶¶ 172-282. Such allegations do not establish an FCA violation unless a false claim was actually submitted for reimbursement. *See Gohil*, 2015 WL 1456664, at *11. In fact, it is almost inconceivable that AstraZeneca's alleged marketing of Crestor as more effective than other statins for lowering cholesterol would lead to

physicians writing prescriptions for uses that were not medically accepted.

There are no facts alleged that create a "strong inference" that AstraZeneca's purported marketing based on the superior efficacy of Crestor led to the submission of claims for ***non-reimbursable*** uses. Indeed, Relators stop well short of making any such allegation. Instead, Relators simply repeat the same conclusory allegation:

> Based on the aforedescribed false and misleading representations, Dr. Bechara wrote Crestor prescriptions, which caused false claims to be submitted to these Government Programs, which in turn paid at least on false claim.

TAC ¶ 184; *see also* ¶¶ 185, 190, 196, 223, 240, 241, 242, 247, 258, 262, 264, 277.

Noticeably absent from such allegations is the assertion that the physician wrote prescriptions for non-reimbursable uses. Relators merely allege that physicians "wrote Crestor prescriptions" and ask the Court to make the untenable leap that such prescriptions were for non-reimbursable uses. This inference is not plausible when the allegations are equally consistent with conduct that does not implicate the FCA: as a result of alleged marketing regarding the superior efficacy of Crestor, physicians wrote prescriptions for various FDA-approved or otherwise medically accepted uses. *See Customs Fraud Investigations*, 2014 WL 4375638, at *14-15 (granting motion to dismiss FCA claims with prejudice where allegations raised possibility of viable FCA claims, but were insufficient to support a reasonable inference that defendant acted deliberately); *Twombly*, 550 U.S. at 570 (holding complaint must be dismissed where plaintiffs' allegations were consistent with lawful conduct and "have not nudged their claims across the line from conceivable to plausible"). Indeed, Relators do not even allege that any prescriptions written based on the purported "superiority" scheme were for non-reimbursable uses.

Similarly, the subset of allegations that AstraZeneca's purported statements to state

Pharmacy & Therapeutics committees led to the inclusion of Crestor on state preferred drug lists ("PDL") (TAC ¶¶ 197-223, 248-52) do not lead to a strong inference that such activity caused the submission of claims for non-reimbursable uses. Relators merely allege that, "[b]ased at least in part on [AstraZeneca's] false representations concerning Crestor's superiority, the Committee voted to retain it on the PDL." *See* TAC ¶ 252; *see also* TAC ¶¶ 250, 215, 217, 219. However, merely adding Crestor to a PDL does not lead to a "strong inference" that claims were submitted for non-reimbursable uses.

2. Allegations Related to Promotion for "Regression of Atherosclerosis" and Prevention of Heart Attacks and Strokes Do Not Lead to a Strong Inference that False Claims Were Submitted to the Government

Relators allege that AstraZeneca improperly utilized published scientific studies to promote Crestor for the regression of atherosclerosis (*see* TAC ¶¶ 283-335) and prevention of heart attacks and strokes (TAC ¶¶ 336-97). Setting aside the fact that there is nothing improper about distributing scientific information to physicians (*see* TAC ¶ 69), these claims fail for two reasons. First, these allegations do not lead to a "strong inference" that claims for regression of atherosclerosis or the prevention of heart attacks and strokes were submitted to government programs. Second, even if such inference were established, "regression of atherosclerosis" and "prevention of heart attacks and strokes" are reimbursable by federal programs and therefore cannot form the basis of FCA liability.

In fact, the TAC stops short of actually alleging that Crestor prescriptions were written or that claims were submitted for the treatment of regression of atherosclerosis or the prevention of heart attacks and strokes. Relators merely describe how AstraZeneca allegedly promoted scientific studies such as ASTEROID, JUPITER, CORONA and METEOR and then conclusorily assert that, "[b]ased on these false and misleading representations, [a physician] wrote Crestor prescriptions, which caused false claims to be submitted to Government Programs,

which in turn paid at least one false claim." TAC ¶ 300; *see also* ¶¶ 307, 308, 311, 313, 314, 319, 329, 331, 332, 345, 387, 388, 389. However, there is simply no inference, let alone allegation, that physicians wrote prescriptions for uses that were not reimbursable. The need for Relators to plead reliable indicia that lead to a strong inference that false claims were submitted is even more acute in this case, where the patient populations for FDA-approved uses of Crestor overlaps significantly with the patient populations of the alleged off-label uses. Because the facts as alleged are consistent with conduct that does not implicate an FCA violation, Relators have not put forth reliable indicia supporting a strong inference that false claims were actually submitted. *Foglia*, 754 F.3d at 156.

Even if Relators had pled that claims for regression of atherosclerosis and reducing the risk of heart attack and strokes were submitted to government programs, such uses are reimbursable by federal programs and thus would not constitute false claims. *See Gohil*, 2015 WL 1456664, at *11. Relators have conceded that Crestor is supported for various non-FDA-approved uses, including "Generalized Atherosclerosis." *See, e.g.*, SAC ¶ 105 (listing uses of Crestor supported by the Drugdex compendium). "Regression of atherosclerosis" – the off-label use referenced by Relators throughout the TAC – is consistent with and subsumed within this "medically accepted" use, and is therefore reimbursable. Similarly, even before Crestor's FDA-approved indication for the treatment of heart attacks and strokes, Drugdex supported the use of Crestor for "Generalized Atherosclerosis," "Disorder of Cardiovascular System, Primary; Prophylaxis," and "Acute Coronory Syndrome," all of which implicate prevention of heart attack and stroke. *See* SAC ¶ 105.

Because the TAC fails to support the conclusion that, as a result of the alleged promotional efforts, claims were submitted for uses that are not reimbursable by federal

programs, the TAC should be dismissed.

3. Relators Fail to Allege An FCA Claim Related to the Promotion of Crestor for Prevention of Diabetes, Renal Protection, Reduction of Proteinuria, and for its "Pleiotropic" Effects

In their attempt to bolster their TAC, Relators throw in conclusory allegations concerning AstraZeneca's supposed promotion of Crestor for the prevention of diabetes, renal protection, reduction of proteinuria and for its "pleiotropic" effects. *See* TAC ¶¶ 398-428. However, Relators again fail to establish a "strong inference" that claims were submitted for non-reimbursable uses. Relators never allege that a physician wrote a prescription to prevent or delay the onset of diabetes or for Crestor's other "pleiotropic" effects. *See* TAC ¶¶ 401, 424. Instead, Relators use the same conclusory language that they use throughout the TAC, which merely alleges "physician[s] wrote Crestor prescriptions" without specifying the use. Further, with respect to Relators' allegations concerning "Renal Protective Effects" (TAC ¶¶ 409-12) and "Alzheimer's Disease and Dementia" (TAC ¶¶ 425-28), Relators do not allege that AstraZeneca's alleged promotional activities led to any prescriptions being written or submitted to the government for payment. Accordingly, these seemingly throw-away allegations fail to support an FCA claim. *See United States ex rel. Piacentile v. Sanofi Synthelabo, Inc.*, No. 05-2927, 2010 WL 5466043, at *7-9 (D.N.J. Dec. 30, 2010).

C. Relators' AKS Claims Should be Dismissed for Failure to State Any FCA Claims with Plausibility or Particularity Under Fed. R. Civ. P. 8(a) and 9(b)

Relators allege that, as part of its off-label promotion scheme, AstraZeneca paid kickbacks to healthcare professionals, in the form of speaking fees, CMEs, dinner events and preceptorships, in violation of the AKS. *See* TAC ¶¶ 435-511. The AKS does not prohibit all business transactions between physicians and drug companies. *See, e.g., United States v. Ctr. for Diagnostic Imaging, Inc.*, 787 F. Supp. 2d 1213, 1223 (W.D. Wash. 2011) (explaining that

"remuneration" element of AKS claim must be assessed in light of fair market value for service rendered); *Cooper v. Pottstown Hosp. Co.* , No. 13-01137, 2015 WL 1137664, at *4 (E.D. Pa. Mar. 13, 2015) (finding plaintiff failed to state AKS claim where he failed to "allege that he was compensated in excess of fair market value"). Rather, to establish a violation of the AKS, Relators must prove four elements: (1) knowing and willfully, (2) offering or paying remuneration, (3) to induce another to purchase a good or service, (4) for which payment may be made by a federal healthcare program. 42 U.S.C. § 1320a-7b(b)(2)(B).

Under Rule 9(b) and the basic plausibility standard of *Iqbal* and *Twombly*, a relator may not avoid dismissal by simply alleging facts that are equally consistent with lawful conduct and attach to them the label "kickback." *See Twombly*, 550 U.S. at 570.

Yet, that is exactly what Relators have tried to do here. For example, Relators allege that certain doctors were paid speaking fees to give presentations about Crestor and that these payments constituted AKS violations. *See, e.g.*, TAC ¶¶ 446, 451, 453, 454. However, while Relators allege specific fees paid to physicians, they fail to allege that these fees were for anything other than the fair market value of the physicians' services. In fact, Relators repeatedly concede that the remuneration paid by AstraZeneca was "in exchange for [the physician's] services." *See* TAC ¶¶ 446, 451, 453, 454. The mere fact that physicians who were compensated for providing a speaking service to AstraZeneca also wrote prescriptions of Crestor does not establish that doctors prescribed Crestor in return for payments of speaking fees, rather than based on their own professional judgment. Relators have therefore failed to plausibly allege remuneration within the meaning of the AKS. *See Ctr. for Diagnostic Imaging*, 787 F. Supp. 2d at 1223 (granting motion to dismiss discounted services claim under AKS and FCA).[7]

[7] *But see United States ex rel. Boise v. Cephalon, Inc.*, No. 08-287, 2015 WL 1724572 (E.D. Pa. Apr. 15, 2015). Although the court in *Boise* found that Relators did not need to allege facts

Relators' other AKS allegations fail for similar reasons:

- Relators allege that AstraZeneca sponsored CME programs (which are lawful) that were offered as "a free inducement to thousands of physicians throughout the United States." TAC ¶¶ 457-77. These allegations are entirely conclusory and do not articulate why a CME is considered "remuneration" or identify a single physician who was actually induced.

- Relators allege that AstraZeneca used Advisory Boards (which are lawful) to persuade formulary decision makers. TAC ¶¶ 478-84. Relators fail to identify anyone involved with these boards, allege that payment was other than fair market value for services, or allege that such conduct actually led to false claims being submitted.

- Relators allege that AstraZeneca provided kickbacks to NCEP ATP III Guidelines authors to induce them to support of Crestor. TAC ¶¶ 485-95. The TAC, however, only alleges the amount one author was paid by statin manufacturers generally from 2001-2003, before Crestor came to market. TAC ¶ 493.

- Relators allege that AstraZeneca "entertained" physicians with "lavish dinners." TAC ¶¶ 496-502. Relators fail to provide any specifics to support these bare accusations, such as where these dinners were held, the actual cost of such dinners, and whether there was a business purpose to the dinner. Without such specificity, the allegations lead equally to an inference of lawful conduct, *i.e.* physicians were treated to modest meals (as judged through industry standards) while attending a meeting for a legitimate purpose. *See* TAC ¶ 498.

- Relators allege that AstraZeneca used "tutorials," "journal clubs" and "preceptorships" to "disguise illegal payment of kickbacks to physicians." TAC ¶¶ 503-11. Relators fail to allege any particular facts from which it can be reasonably inferred that a $250 preceptorship or dinner was not an appropriate payment, or that doctors were "induced" to prescribe Crestor in exchange, rather than as a result of making their own independent judgment.

In sum, while Relators have highlighted various means by which AstraZeneca lawfully compensates physicians, they have failed to allege specific facts that allow for an inference that such conduct violated the AKS, that such conduct actually induced physicians to prescribe

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regarding fair market value, the *Boise* Relators alleged that physicians were kept on defendant's payroll even though the physicians did not actually perform any speaking services and that appointment as a promotional speaker was a reward for prescribing high amounts of defendant's products off-label. *See id.* at *3-4. Here, Relators' allegations are all tied to actual services performed by physicians.

Crestor, or that such prescriptions were submitted for reimbursement. Accordingly, Relators' AKS violations are not plausible or pled with adequate specificity, and should be dismissed. *See Twombly*, 550 U.S. at 570.

D. Relators' Claims and Allegations Relating to Pre-2007 Conduct Are Barred by the Statute of Limitations

FCA claims are subject to a six-year statute of limitation, running from the date on which the violation occurred. 31 U.S.C. § 3731(b)(1). Although Relators' original complaint was filed in 2010, Relators waited until they filed their TAC on March 5, 2015 to bring claims concerning AstraZeneca's alleged conduct from 2003 through 2006. *Compare* SAC ¶ 2 ("Defendants engaged in a scheme since at least 2007 . . . .")[8] *with* TAC ¶ 1 ("Beginning with the launch of Crestor (rosuvastatin) in September 2003 AstraZeneca deployed a fraudulent marketing scheme."). Accordingly, Relators' claims regarding AstraZeneca's conduct from 2003 through 2006 – raised for the first time more than nine years after the alleged violations – are time-barred.

Fed. R. Civ. P. 15(c) limits when an amendment can relate back to the original pleading to claims "that arose out of the conduct, transaction, or occurrence set out – or attempted to be set out – in the original pleading." Fed. R. Civ. P. 15(c)(1)(B). Because, Relators' new 2003-2006 claims relate to a distinct time period that predates any claims in Relators' original pleading, they are not based on the same "conduct, transaction, or occurrence" as the original pleading. *See United States ex rel. Health Outcomes Techs. v. Hallmark Health Sys., Inc.*, 409 F. Supp. 2d 43, 52-53 (D. Mass. 2006); *Reyes v. United States*, No. CIV A 04-1952 JAG, 2007 WL

[8] Although Relators clearly asserted that AstraZeneca's alleged scheme did not begin until 2007, the SAC does reference certain conduct occurring in 2006 related to the release of the ASTEROID study. *See* SAC ¶¶ 151, 153, 155-56. Should the Court find these allegations sufficient, then Relators' claims that pre-date the release of the ASTEROID study in 2006 should be barred by the FCA's statute of limitations.

38852, at *6 (D.N.J. Jan. 4, 2007).

E. Relators' State Law Claims Should Be Dismissed

1. Relators' State Law Claims Should Be Dismissed for the Same Reasons as the Federal Claims; Alternatively, the Court Should Decline to Exercise Supplemental Jurisdiction

As Relators' federal claims fail under Rules 8(a), 9(b), and 12(b)(6), their state law claims, which rely on the same allegations, should also be dismissed. *See, e.g.*, *Christidis v. First Pa. Mortg. Trust*, 717 F.2d 96, 99 (3d Cir. 1983) (explaining that Rule 9(b) applies "not only to fraud actions under federal statutes, but to fraud claims based on state law"); *Foglia v. Renal Ventures Mgmt., LLC*, 830 F. Supp. 2d 8, 13 (D.N.J. 2011) (applying Rule 9(b) to allegations under false claim statutes of New Jersey and Texas); *Leder v. Shinfeld,* 609 F. Supp. 2d 386, 396 (E.D. Pa. 2009) (dismissing state law claim for failure to comply with Rule 9(b)).

Moreover, "[i]n the usual case in which all federal-law claims are dismissed before trial, the balance of factors to be considered under the pendent jurisdiction doctrine—judicial economy, convenience, fairness, and comity—will point toward declining to exercise jurisdiction over the remaining state-law claims." *United States ex rel. Digital Healthcare, Inc. v. Affiliated Computer Servs., Inc.*, 778 F. Supp. 2d 37, 55 (D.D.C. 2011) (internal quotation marks and citation omitted). This Court should exercise its discretion to decline supplemental jurisdiction over the state claims. *See* 28 U.S.C. § 1367(c)(3); *see also United States ex rel. Simpson v. Bayer Corp.*, Civil Action No. 05-3895, 2012 WL 3600302, at *5 (D.N.J. Aug. 21, 2012); *Digital Healthcare, Inc.*, 778 F. Supp. at 54-55 (same); *see also Kusner v. Hepburn, Willcox, Hamilton & Putnam*, Civil Action No. 00-6313, 2001 WL 34368779, at *5 (E.D. Pa. Nov. 21, 2001).

2. Certain of the State Law Claims Should be Dismissed for Independent Reasons

a. Where State Statutes Require Intervention or Action by the State, Relators' Claims Must Be Dismissed

Under the applicable, earlier version of the Delaware False Claims and Reporting Act, a relator may continue a *qui tam* action in which the state does not intervene only when the Delaware Attorney General issues a "written determination" that there is "substantial evidence" of a violation. *See* Del. Code. Ann. Tit. 6 § 1203(b)(4)(b) (2000);[9] *see also United States ex rel. Streck v. Allergan, Inc.*, 894 F. Supp. 2d 584, 603 (E.D. Pa. 2012) ("[F]or a *qui tam* action to continue without state intervention, the Attorney General (in Delaware) . . . must issue a written determination, that there is substantial evidence that a violation occurred."). Relators do not allege that the Delaware Attorney General issued written determinations of "substantial evidence that a violation" occurred. Thus, Relators lack authority to pursue claims under Delaware's false claims statute for conduct pre-dating July 16, 2009, and this claim (Count VI) should be dismissed.

A similar state statute bars Relators' New Mexico claims (Count XXII). *See* New Mexico False Claims Act, N.M. Stat. § 27-14-7(E)(2). Where, as here, the state "declines to take over the action," a *qui tam* relator may only proceed upon a determination "that there is substantial evidence" of a statutory violation. *Id.* Relator has not alleged that New Mexico made such a determination; therefore, this count must be dismissed.

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[9] This requirement was eliminated from the Delaware Act in a July 16, 2009 amendment. 2009 Del. Laws Ch. 166 § 10 (S.B. 115). "[A]bsent a clear legislative intent, Delaware courts will not infer an intention to make an act retroactive." *Wilson v. Triangle Oil Co.*, 566 A.2d 1016, 1018 (Del. Super. Ct. 1989), *aff'd sub nom. Clark v. Sun Ref. & Mktg. Co.*, 584 A.2d 1228 (Del. 1990). Accordingly, this requirement applies to conduct alleged prior to July 16, 2009.

b. Relators' Claims Should Be Dismissed to the Extent They Rely on the Retroactive Application of State Law

This Court should dismiss the state claims for Connecticut (Count V), Georgia (Count IX), Iowa (Count XIII), Maryland (Count XV), Minnesota (Count XVIII), New Jersey (Count XXII), North Carolina (Count XXIV),[10] Oklahoma (Count XXV), and Rhode Island (Count XXVI), to the extent that the TAC alleges conduct occurring prior to the effective date of those states' false claims acts.[11] It is well-established that "[r]etroactivity is generally disfavored in the law," *Eastern Enters. v. Apfel*, 524 U.S. 498, 532 (1998) and that, absent express legislation to the contrary, statutes apply prospectively only. *Sikora v. Am. Can Co.*, 622 F.2d 1116, 1125 (3d Cir. 1980). This presumption against retroactivity applies equally to state FCA claims. *See, e.g.*, *Graham Cnty. Soil & Water Conserv. Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 283 n.1 (2010); *Massachusetts v. Schering-Plough Corp.*, 779 F. Supp. 2d 224, 238 (D. Mass. 2011) (holding that retroactive application of Massachusetts FCA would violate *ex post facto* clause of the Constitution).

Moreover, each of these states endorses a presumption against retroactivity.[12] Thus, with

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[10] *See* N.C. Gen. Stat. § 1-605 (2009). North Carolina's False Claims Act became effective January 1, 2010. *Id.* The statute only allows a retroactive claim to the extent it is "based on acts committed prior to that date if the activity would also be covered under Part 7 of Article 2 of Chapter 108A of the General Statutes and if the limitation period . . . has not lapsed." *Id.* at Notes. The referenced statutory section, North Carolina General Statute § 108A-70.10, applies specifically to violations by "any provider of medical assistance," where the provider presents, or causes to be presented a false claim, or makes, uses, or causes to be made or used a false record. N.C. Gen. Stat. § 108A-70.10. Thus, the North Carolina FCA is applied retroactively only for claims against a provider of medical assistance, which AstraZeneca is not.

[11] Conn. Gen. Stat. § 17b-301a (effective October 5, 2009); Ga. Code § 49-4-168 et seq. (effective May 24, 2007); Iowa Code 685.2 et seq. (effective July 1, 2010); Md. Code. Ann., Health-Gen § 2-602 et seq. (effective Oct. 1, 2010); Minn. Stat. § 15C.05 (effective July 1, 2010); N.J. Stat. § 2A:32-C1 et seq. (effective Mar. 13, 2008); N.C. Gen. Stat. § 1-605 (effective Jan. 1, 2010); Okla. Stat. tit. 63 § 5053.1 et seq. (effective Nov. 1, 2007); R.I. Gen. Laws § 9-1.1.-1 et seq. (effective July 1, 2007).

[12] *See Enfield Fed. Sav. & Loan Ass'n v. Bissell*, 440 A.2d 220, 221 (Conn. 1981) (holding that there is a presumption to apply legislation prospectively, unless it is an amending statute that is

respect to the counts arising under these states' laws, any claims based on conduct occurring prior to the effective dates of the relevant statutes should be dismissed. *See Streck*, 894 F. Supp. 2d at 604-05 (dismissing state law claims to the extent the conduct occurred prior to the enactment of the respective states' false claims acts).

c. Count XXII Should Be Dismissed for Lack of Standing

Count XXII asserts that AstraZeneca's alleged conduct violated the New Mexico Medicaid False Claims Act, N.M. Stat. § 27-14-1 et seq. *See generally* TAC ¶¶ 695-702. Under the statute, only "affected persons" may bring private civil actions. N.M. Stat. § 27-14-7(B). The term "affected persons" is not defined under New Mexico law; however, federal courts have unambiguously found that residents of states other than New Mexico are not "affected persons." *See United States ex rel. King v. Solvay S.A.*, 823 F. Supp. 2d 472, 520-21 (S.D. Tex. 2011), *order vacated in non-relevant part on reconsideration by*, 2012 WL 1067228 (S.D. Tex. Mar. 28, 2012). Foote is a resident of Indiana. TAC ¶ 22. Lorden is a resident of New Hampshire. TAC ¶ 29. Therefore, they both lack standing to assert a claim under the New Mexico Medicaid False Claims Act and Count XXII of the TAC must be dismissed.

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procedural in its impact); *Fowler Props., Inc. v. Dowland*, 646 S.E.2d 197, 200 (Ga. 2007) ("[L]egislation which affects substantive rights may only operate prospectively."); *City of Monticello v. Adams*, 200 N.W.2d 522, 525 (Iowa 1972) ("The courts have evolved a strict rule of construction against a retrospective operation."); *Scroggins v. Dahne*, 645 A.2d 1160, 1163 (Md. 1994) ("[A] statute is presumed to have prospective effect only, unless there is a clear legislative intent that the statute operate retroactively."); *In re Alexandria Lake Area Sanitary District NPDES/SDS Permit No. MN0040738*, 763 N.W.2d 303, 309 n.8 (Minn. 2009) ("Minnesota laws are presumed to have no retroactive effect unless clearly and manifestly intended by the legislature."); *State ex rel. Hayling v. Corr. Med. Servs., Inc.*, 28 A.3d 1246, 1250-51 (N.J. Super. Ct. 2011) (applying "general rule of statutory construction that favors prospective application of statutes" to New Jersey False Claims Act); *Cole v. Silverado Foods, Inc.*, 78 P.3d 542, 546 (Okla. 2003) ("Absent a plain legislative intent to the contrary, statutes are generally presumed to operate prospectively only."); *Direct Action for Rights & Equality v. Gannon*, 819 A.2d 651, 658 (R.I. 2003) ("Ordinarily, this Court presumes that statutes and their amendments operate prospectively . . . .").

F. Pursuant to Rule 12(b)(1), Relator Lorden's Claims Should Be Dismissed for Lack of Subject Matter Jurisdiction

Under the FCA's first-to-file rule, this Court lacks subject matter jurisdiction over Lorden's claims because Lorden filed his claims ***after*** Foote's Complaint was pending (*compare* D.I. 2, *with* D.I. 7) and ***after*** RoseMarie De Souza filed her related FCA action on February 15, 2010 (De Souza Action, D.I. 1).

1. Applicable Law

In non-intervened cases, the FCA bars *qui tam* relators from pursuing actions that are based on the facts underlying a prior-filed action. 31 U.S.C. § 3730(b)(5); *see, e.g., United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc.*, 149 F.3d 227, 232 (3d Cir. 1998). "This 'first to file bar' is 'exception free.'" *United States ex rel. Piacentile v. Sanofi Synthelabo, Inc.*, No. 05-2927 (KSH), 2010 WL 5466043, at *4 (D.N.J. Dec. 30, 2010).

The first-to-file bar applies equally when additional relators join an existing case. For example, in *Palladino ex rel. United States v. VNA of S. N.J., Inc.*, the court held that the second relator, who joined the first-filed relator's action, was barred from bringing her *qui tam* claim because her allegations were encompassed by the first relator's action. 68 F. Supp. 2d 455, 477-79 (D.N.J. 1999). Likewise, in *United States ex rel. Simpson v. Bayer Corp.*, No. 05-3895, 2012 WL 3600302, at *6 (D.N.J. Aug. 21, 2012), the court struck an amended complaint in its entirety which purported to add an additional relator in violation of the first-to-file rule.

Courts in other districts have similarly applied the first-to-file rule to bar additional relators from joining an existing case. *See, e.g., United States ex rel. Nowak v. Medtronic, Inc.*, 806 F. Supp. 2d 310, 335 & n.14 (D. Mass. 2011) (dismissing second relator's claims from consolidated complaint and finding "[w]here this court lacks jurisdiction over the claims of a later-added relator due to the first-to-file rule, those claims attributable to that relator – and that relator –

must be dismissed" (citation omitted)); *United States ex. rel. Denenea v. Allstate Ins. Co.*, No. 07-2795, 2011 WL 231780, at *3 (E.D. La. Jan. 24, 2011) ("[A] relator cannot avoid the first-to-file bar by consolidating his claim with an earlier action."); *United States ex rel. Manion v. St. Luke's Reg'l Med. Ctr., Ltd.*, No. 06-498, 2008 WL 906022, at *6-7 (D. Idaho Mar. 31, 2008) ("The statute not only prevents a person from bringing a 'related action' but also from intervening in any way. Adding Smyth to the complaint would constitute intervening when using the plain meaning of the term.").[13]

2. Relator Lorden Joined An Earlier Filed Qui Tam Action in Contravention of the First-to-File Rule

Here, Lorden joined Foote's Action ***after*** Foote's original complaint was filed. *See* D.I. 7 (Amended Complaint adding Lorden as a Relator). However, Lorden's claims and allegations are merely details of the fraudulent scheme insufficiently alleged by Foote in his original complaint. *See* SAC ¶¶ 146, 164, 173, 177, 205, 206, 215, 221, 246. As such, Lorden's claims are barred in their entirety. *See LaCorte*, 149 F.3d at 234 ("[D]uplicative claims do not help reduce fraud or return funds to the federal fisc, since once the government knows the essential facts of a fraudulent scheme, it has enough information to discover related frauds.").

Moreover, Lorden's claims are barred by the De Souza Action because the De Souza

[13] *But see United States ex rel. Precision Co. v. Koch Indus., Inc.*, 31 F.3d 1015, 1017-18 (10th Cir. 1994) (holding sole shareholders could be added to complaint originally brought by plaintiff-corporation); *United States ex rel. Boise v. Cephalon, Inc.*, No. 08-287, 2014 WL 5089671, at *2-3 (E.D. Pa. Oct. 9, 2014) (relying on *Precision*); *United States v. Educ. Mgmt. Corp.*, 871 F. Supp. 2d 433, 460 (W.D. Pa. 2012) (same). The *Precision* opinion and its progeny, however, have been criticized as "contrary to the statutory language and should not be followed." John T. Boese, Civil False Claims and Qui Tam Actions, § 4.03[c] (4th ed.) (emphasis added); *see also Manion*, 2008 WL 906022, at *7 (declining to follow the ruling in *Precision*). Courts in this circuit have consistently looked to Boese's authoritative treatise in their analysis of FCA cases. *See United States v. Sodexho, Inc.*, CIV.A. 03-6003, 2009 WL 579380, at *16 (E.D. Pa. Mar. 6, 2009).

Action was pending at the time Lorden filed his claims.[14] De Souza filed her Action on February 15, 2010, *see* De Souza Action, D.I. 1, while Lorden did not bring any of his claims until March 30, 2010, the date the Amended Complaint was filed. D. I. 7. For this additional reason, Lorden and his claims must be dismissed.

G. Relators' Claims Should Be Dismissed With Prejudice

Despite being the third attempt, the TAC fails to comply with the relevant pleading standards. Moreover, there is no indication that Relators, if given another opportunity to amend, would be able to meet those standards. Since Relators were terminated by AstraZeneca in October 2009 and February 2010, respectively (TAC ¶¶ 22, 30), they would have no direct or independent knowledge of any conduct not already contained in the existing iterations of the complaint. In situations such as this, "a curative amendment need not be afforded where it 'would be inequitable or futile.'" *Barnard v. Verizon Commc'ns, Inc.*, 451 F. App'x 80, 87 (3d Cir. 2011) (citing *Phillips v. County of Allegheny*, 515 F.3d 224, 245 (3d Cir. 2008)). In a similar FCA case, where Relators were previously provided multiple opportunities to amend, the court dismissed Relators' claims with prejudice. *See United States ex rel. Garcia v. Novartis AG*, No. 06-1465-WGY, -- F. Supp. 3d --, 2015 WL 1206122, at *21 (D. Mass. Mar. 17, 2015). The court reasoned that Relators had six years, from the time Relators filed their original complaint to when the most recent amended complaint was filed, to gather evidence and bring it to the court's attention, yet Relators failed to do so. *See id.* Here, Relators have had five years to

[14] Although De Souza's FCA claims have since been dismissed, *see* D.I. 90, the De Souza Action is still considered a "pending action" for purposes of the first-to-file analysis because the action was pending at the time Lorden filed his claims. *See United States ex rel. Shea v. Cellco P'ship*, 748 F.3d 338, 343 (D.C. Cir. 2014) (finding that "[t]he simplest reading of 'pending' is the referential one; it serves to identify which action bars the other"); *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 32 (1st Cir. 2009). On July 1, 2014 the Supreme Court granted certiorari in *United States ex rel. Carter v. Halliburton Co.* to address this issue of whether § 3730(b)(5) bars later related actions once an earlier-filed action has been dismissed. 710 F.3d 171 (4th Cir. 2013), *cert. granted*, -- U.S. --, 134 S. Ct. 2899 (2014).

gather evidence and are still unable to add sufficient facts to meet their pleading requirements; thus, further amendment would be futile. *See id.* ("A court may deny leave to amend for the 'repeated failure to cure deficiencies, and futility of amendment.'") (citation omitted).

Further, it would be inequitable for AstraZeneca to have to incur additional costs of responding to another unsuccessful complaint. *See, e.g., Cureton v. NCAA*, 252 F.3d 267, 273 (3d Cir. 2001) (denying leave to amend when allowing such an amendment "would result in additional discovery, cost, and preparation to defend against new facts or new theories").

V. CONCLUSION

For each of the reasons stated above, the Court should dismiss the TAC with prejudice.

April 24, 2015

MORGAN, LEWIS & BOCKIUS LLP

/s/ Jody C. Barillare

Jody C. Barillare (#5107)
The Nemours Building
1007 North Orange Street, Suite 501
Wilmington, DE 19801
(302) 574-3000
jbarillare@morganlewis.com

John C. Dodds (admitted *pro hac vice*)
Rebecca J. Hillyer (admitted *pro hac vice*)
Evan K. Jacobs (admitted *pro hac vice*)
1701 Market Street
Philadelphia, PA 19103-2921
(215) 963-5000
jdodds@morganlewis.com
rhillyer@morganlewis.com
ejacobs@morganlewis.com

Attorneys for Defendant AstraZeneca Pharmaceuticals LP